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June 22, 2004

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Commissioner of Patents  
U.S. Patent and Trademark Office  
220 20<sup>th</sup> Street S.  
Customer Window, **MS Amendment**  
Crystal Plaza Two, Lobby, Room 1B03  
Arlington, VA 22202

Re: Supplemental Information Disclosure Statement  
Appl. No.: 10/612,338  
Filed: July 3, 2003  
Title: **Compositions and Methods Involving the  
Combination of a Thromboxane A2 Receptor  
Antagonist and an Inhibitor of Cyclooxygenase-2**  
Inventor(s): Brunner, Hans R.  
Atty. Dkt.: 7571/80526

Sir:

The following documents are being forwarded for appropriate action by the U.S. Patent and Trademark Office:

1. Supplemental Information Disclosure Statement;
2. PTO Form-1449, List of References Cited by Applicant;
3. References A1-A6, B1-B6 and C1-C15; and
4. Return postcard.

Commissioner of Patents  
June 22, 2004  
Page 2

**Applicant does not believe that any fee is due for the filing of this Information Disclosure Statement. However, the Commissioner is hereby authorized to charge any fee deficiency with respect to this filing and any other fee required in connection with the present case, or credit any overpayment, to our Deposit Account No. 06-1135 under Order No. 7571/80526.**

It is respectfully requested that the enclosed postcard be stamped with the date the enclosed documents are received by the PTO and that it be returned as soon as possible.

Respectfully submitted,

FITCH, EVEN, TABIN & FLANNERY

A handwritten signature in black ink that reads "Michael A. Sanzo". The signature is written in a cursive, flowing style.

Michael A. Sanzo  
Attorney for Applicant  
Registration No. 36,912

MAS:ct  
Enclosures



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of:

Brunner, Hans R.

Appl. No.: 10/612,338

Filed: July 3, 2003

For: **Compositions and Methods Involving  
the Combination of a Thromboxane  
A2 Receptor Antagonist and an Inhibitor  
of Cyclooxygenase-2**

Art Unit: to be assigned

Examiner: to be assigned

Atty. Dkt.: 7571/80526

**Supplemental Information Disclosure Statement**

Commissioner of Patents  
U.S. Patent and Trademark Office  
2011 South Clark Place  
Customer Window, **MS Amendment**  
Crystal Plaza Two, Lobby, Room 1B03  
Arlington, VA 22202

Sir:

Submitted herewith is a listing of documents known to Applicant and/or his attorney in compliance with the requirements of 37 C.F.R. § 1.56. Copies of the listed documents are also enclosed.

In accordance with 37 C.F.R. § 1.98(a)(3), Applicants' undersigned attorney submits the following concise explanation of the relevance of the non-English language document cited on the accompanying form:

Reference B2, published international patent application WO 92/02494, describes cyclopentene thromboxane-A2 antagonists that can be used for treating cardiovascular disorders, migraine, allergies and other conditions. The compounds have also been found to have a cyto-protective effect. An English language abstract corresponding to this document is cited on the accompanying list of references as document C14.

Reference B4, published international patent application WO 92/19270, describes calcium/serotonin and thromboxane 2 receptor antagonists. Drug compositions containing these antagonists are useful in treating coronary heart conditions and arterial occlusion disorders by inhibiting thrombosis and vasospasticity. An English language abstract corresponding to this document is cited on the accompanying list of references as document C15.

Applicant does not waive any rights to appropriate action to establish patentability over any of the listed documents should they be applied as references against the claims of the present application. This statement should not be construed as a representation that more material information does not exist or that an exhaustive search of the relevant art has been made.

Consideration of the cited documents and making the same of record in the prosecution of the above-captioned application are respectfully requested.

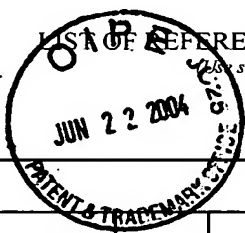
Applicant does not believe any fee is due for the submission of this Information Disclosure Statement. However, the Commissioner is hereby authorized to charge any fee deficiency to our Deposit Account No. 06-1135 under Order No. 7571/80526.

Respectfully submitted,

FITCH, EVEN, TABIN & FLANNERY

By Michael A. Sanzo  
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 <p>LIST OF REFERENCES CITED BY APPLICANT (Use several sheets if necessary)</p>				Atty. Docket No.: 7571/80526		Appl. No.: 10/612,338			
				Applicant(s) Brunner, Hans R.					
				Filing Date: July 3, 2003		Group: to be assigned			
U.S. PATENT DOCUMENTS									
Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate		
	A 1	5,605,917	Feb. 25, 1997	Ogletree	514	365	Dec. 22, 1994		
	A 2	5,872,145	Feb. 16, 1999	Plachetka	514	415	Aug. 14, 1997		
	A 3	6,060,499	May 9, 2000	Plachetka	514	415	Sep. 11, 1998		
	A 4	6,077,539	Jun. 20, 2000	Plachetka, <i>et al.</i>	424	474	Nov. 10, 1997		
	A 5	6,479,551 B1	Nov. 12, 2002	Plachetka, <i>et al.</i>	514	619	Mar. 3, 2000		
	A 6	6,586,458 B1	Jul. 1, 2003	Plachetka	514	415	Apr. 27, 2000		
	A 7								
	A 8								
	A 9								
	A 10								
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	A 25								
	A 26								
	A 27								
Examiner				Date Considered					

<b>LIST OF REFERENCES CITED BY APPLICANT</b> <i>(Use several sheets if necessary)</i>				Atty. Docket No.: 7571/80526		Appl. No.: 10/612,338		
				Applicant(s) Brunner, Hans R.				
				Filing Date: July 3, 2003		Group: to be assigned		
<b>FOREIGN PATENT DOCUMENTS</b>								
Examiner Initial		Document Number	Date	Country	Class	Subclass	Abst./Trans.	
							Yes	No
	B 1	WO 91/13062	Sep. 5, 1991	WIPO	C07D	233/61		
	B 2	WO 92/02494	Feb. 20, 1992	WIPO	C07C	405/00	X	
	B 3	WO 92/19182	Nov. 12, 1992	WIPO	A61F	2/02		
	B 4	WO 92/19270	Nov. 12, 1992	WIPO	A61K	45/06	X	
	B 5	WO 99/45905	Sep. 16, 1999	WIPO	A61K	31/00		
	B 6	GB 2 038 821	Jul. 30, 1980	United Kingdom	C07D	233/60		
	B 7							
	B 8							
	B 9							
	B 10							
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	B 27							
Examiner				Date Considered				

<b>LIST OF REFERENCES CITED BY APPLICANT</b> <i>(Use several sheets if necessary)</i>		Atty. Docket No.: 7571/80526	Appl. No.: 10/612,338
		Applicant(s) Brunner, Hans R.	
		Filing Date: July 3, 2003	Group: to be assigned
Examiner Initial	OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)		
	C 1	BEASLEY, <i>et al.</i> , "Effect of a Thromboxane Receptor Antagonist on PGD <sub>2</sub> and Allergen-Induced Bronchoconstriction," <i>J. Appl. Physiol.</i> 66:1685-1693 (1989).	
	C 2	BELLEVANCE, <i>et al.</i> , "A Comparative Study of Naproxen Sodium, Pizotyline and Placebo in Migraine Prophylaxis," <i>Headache</i> 30:710-715 (1990).	
	C 3	CADY, <i>et al.</i> , "Treatment of Acute Migraine with Subcutaneous Sumatriptan," <i>JAMA</i> 265:2831-2835 (1991).	
	C 4	DeMAIS, <i>et al.</i> , "Thromboxane A <sub>2</sub> Receptor Antagonists. Synthesis and Activities of Phenylsulfonamido Derivatives," <i>Eur. J. Med. Chem.</i> 26:821-827 (1991).	
	C 5	DIAMOND, <i>et al.</i> , "Long-Term Study of Propranolol in the Treatment of Migraine," <i>Headache</i> 22:268-271 (1982).	
	C 6	FITZGERALD, <i>et al.</i> , "Role of Thrombin and Thromboxane A <sub>2</sub> in Reocclusion Following Coronary Thrombolysis with Tissue-Type Plasminogen Activator," <i>Proc. Natl. Acad. Sci. USA</i> 86:7585-7589 (1989).	
	C 7	HIRATA, <i>et al.</i> , "Roles of Platelet-Activating Factor, Thromboxane A <sub>2</sub> , ADP and Thrombin in Thrombogenesis in the Guinea Pig," <i>Eur. J. Pharmacol.</i> 231:421-425 (1993).	
	C 8	KURITZKY, "Sodium Valproate in the Prophylactic Treatment of Migraine: a Double-Blind Study Versus Placebo," <i>Cephalalgia</i> 12:81-84 (1992).	
	C 9	LUMLEY, <i>et al.</i> , "The Effects of GR32191, a New Thromboxane Receptor Blocking Drug, on Platelets and Vascular Smooth Muscle in Vitro," <i>Thrombosis and Haemostasis</i> 58:261 (1987).	
	C 10	MYOU, <i>et al.</i> , "Inhibitory Effect of a Selective Thromboxane Synthetase Inhibitor, OKY-046, on Acetaldehyde-Induced Bronchoconstriction in Asthmatic Patients," <i>Chest</i> 106:1414-1418 (1994).	
	C 11	TEMPLETON, <i>et al.</i> , "The Role of Endogenous Thromboxane in Contractions to U46619, Oxygen, 5-HT and 5-CT in the Human Isolated Umbilical Artery," <i>Br. J. Pharmacol.</i> 103:1079-1084 (1991).	
	C 12	YOUNG, "Appropriate Use of Ergotamine Tartrate and Dihydroergotamine in the Treatment of Migraine: Current Perspectives," <i>Headache</i> 37(Supp. 1):S42-S45 (1997).	
	C 13	ZIEGLER, <i>et al.</i> , "Migraine Prophylaxis. A Comparison of Propranolol and Amitriptyline," <i>Arch. Neurol.</i> 44:486-489 (1987).	
	C 14	English language abstract for WO 92/02494, Reference B2 above.	
	C 15	English language abstract for WO 92/19270, Reference B4 above.	
	C 16		
	C 17		
	C 18		
	C 19		
Examiner		Date Considered	